REMARKS / ARGUMENTS

1. STATUS OF CLAIMS

Claims 1-14, 52-54, and 57-62 are pending.

Applicant acknowledges with appreciation the Examiners withdrawal of the restriction requirement of the pending claims.

Claims 52 and 54 are amended to correct the antecedent basis so that these claims properly refer to the elements, "microspheres and nanospheres" recited earlier within the claims.

2. EXAMINER'S REJECTIONS

The Examiner, in a Non-Final Office Action mailed September 30, 2008, rejected all of the pending claims in the application.

A. Claims 52-54 were rejected under 35 U.S.C. § 112 (2nd) as being indefinite for failing to distinctly claim the subject matter which Applicant regards as the invention.

B. Claims 1, 3-13, 52, 53, and 57-62 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Royds et al., U.S. 5,466,465 ("Royds") in view of Ishihara, U.S. 5,190,766 ("Ishihara").

C. Claims 1-14, 52, 53, and 57-62 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Royds and Ishihara as applied to claims 1, 3-13, 52, 53, and 57-62 and further in view of Zeimer et al., U.S. 4,891,043 ("Zeimer").

3. ARGUMENTS AGAINST EXAMINER'S REJECTIONS

Applicant respectfully traverses the Examiner's rejections of claims1-14, 52-54, and 57-62. Applicant requests reconsideration and withdrawal of the rejections based on the above claim amendments and the following remarks.

A. REJECTION OF CLAIMS 52-54 UNDER 35 U.S.C. § 112 (2nd) AS BEING INDEFINITE.

Applicant has amended claims 52 and 54 to correct the antecedent basis of "microspheres and nanospheres" recited in the claims. Applicant asserts that the amendment clarifies and now distinctly claims the subject matter of the invention.

Applicant respectfully requests the Examiner to withdraw the indefiniteness rejection of claims 52-54 and allow the claims.

B. REJECTION OF CLAIMS 1, 3-13, 52, 53, AND 57-62 UNDER 35 U.S.C. § 103(a) AS BEING UNPAENTABLE OVER ROYDS IN VIEW OF ISHIHARA.

The Examiner asserts that Royds teaches a transdermal drug delivery system comprising a patch wherein a matrix comprising microencapsulated particles of a drug leaches from the particles into the matrix and subsequently passes through the skin of the user. The Examiner admits that Royds does not teach that energy, including ultrasonic energy, is used to selectively release the drug from the microcapsules.

The Examiner asserts that Ishihara discloses the controlled release of a drug from a drug carrier or drug holding structure when irradiated with a sound wave which includes the resonance frequency of the drug carrier. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to use the methods of Ishihara on the transdermal patch of Royds because ultrasound radiation controls the release of the drug.

Applicant respectfully disagrees.

Royds discloses an occlusive patch that entraps sweat from the body, wherein the sweat both hydrates the skin and saturate a matrix comprising a drug in microencapsulated form, and wherein drug release from the microcapsules depends on the relative ease with which water from the entrapped sweat is able to penetrate the microcapsules" coat to dissolve the drug. The dissolved drug leaches from the microcapsule into the matrix and delivered through the skin to exert the desired effect [col 1, ln 56 to col 2, ln 8]. The process is controlled by either selecting the type of coating material for the microcapsule, or by manipulating the constituents of the coating material [col 5, ln 2-13].Royds discloses that the patch comprises a translucent water-impermeable shell or backing layer [col 4, ln 31-42]. Royds discloses that the patch be occlusive (air- and water-tight) to enhance hydration of the skin [col 5, ln 50-55].

Royds does not disclose that ultrasound is used to stimulate release of the drug from the microcapsule.

Ishihara discloses a method which enables the release, within a body, of a given drug from a drug carrier or a drug holding structure. The release is controlled from outside of a body by a resonant sound wave [col 1, ln 7-17 and col 7, ln 33-47]. Ishihara appears to use drug carrier and drug holding structure interchangeably [col 1, ln 7-17 and claims] and defines drug carrier as a gas-containing microcapsule with a drug thereon or therein [col 5, ln 3-16]. Ishihara further defines drug carrier as a microcapsule or particle containing a liquid/sol [col 9, ln 1-12]. Ishihara does not define drug holding structure and provides no description to distinguish drug carrier from drug holding structure. Therefore, Applicant infers that drug carrier

and drug holding structure are the same.

Ishihara discloses that the drug carrier (gas-containing microcapsules) is introduced within the body via injection or through an intravascular catheter [col 6, ln 1-3]. **After** the drug carrier is introduced within the body, a targeted region of the body is irradiated externally (outside of the body) to cause the drug carrier to release the drug, residing within or on the gas-containing microcapsule, within the body [col 7, ln 33-47].

Ishihara does not disclose or suggest that the microcapsules are irradiated outside of the body to release the drug and afterwards the drug leaches into the body. Ishihara does not disclose a method that incorporates a patch. Ishihara does not disclose or suggest a method wherein the microcapsules are within a medium for holding the microcapsules, and wherein the medium is placed on a patch adjacent to the skin of a human or animal, and wherein energy is applied to the patch to release a substance from the microcapsules.

Applicant asserts that the methods of Royds and Ishihara are not compatible and could not be combined to express Applicant's invention as described in the claims. Ishihara discloses that the microcapsules be injected into the body before externally irradiating the body to release the drug from the microcapsules. The microcapsules of Ishihara are not transported into the body through the surface of the skin. Rather the microcapsules are already present within the body prior to being stimulated to release the drug. There would be no reason for one of ordinary skill in the art to expect from the teachings of Ishihara that irradiation of microcapsules outside would cause the drug to be released into a patch and then further absorb into the body.

Royds discloses that the microcapsule are placed in an occlusive patch before applying to the body and only after hydration leached through the surface of the skin. Royds also does not teach or suggest irradiation as a method to release a drug from a microcapsule into a patch and ultimately through the skin. Royds discloses that the water solubility of the drug and permeability through the coating of the microcapsule allows it to be released into the patch and subsequently the body. There is no suggestion or reason for one of ordinary skill in the art to expect from the teachings of Royds or Ishihara that irradiation of the patch would affect the permeability of a drug through the coating of a microcapsule.

Applicant asserts that one of ordinary skill in the art, after reading Ishihara, would have no reason to expect that irradiating a patch with ultrasonic or thermal energy would be an effective method for releasing a drug into the body. Ishihara discloses that a drug releasing method using a planar substrate with a drug applied thereto is defective because "there is no drug releasing effect unless the permissible intensity of sound pressure exceeds the value tolerable to the living body" [col 2, ln 50 to col 3, ln 41]. Ishihara therefore teaches away from a method involving

irradiating a microcapsule on the planar surface of the skin to cause release of a drug through the skin into the body. The combination of Royds and Ishihara does not teach or suggest a method comprising providing a substance "in microcapsules … within a medium…, placing the medium for holding the microcapsules on a surface of a patch adjacent the skin of a human or animal, and applying energy to the patch...thereby resulting in release of the substance from the microcapsules," as recited by Applicant in claim 1.

Neither Ishihara nor Royds disclose or suggest a method "wherein ultrasonic energy applied to the patch at a resonant frequency for certain or all of the microcapsules, thereby rupturing them" as recited in Applicant's claim 3 and paraphrased in claims 52 and 57. The gas-containing microcapsules of Ishihara receive radiation after they have been injected into the body. The microcapsules of Royds remain intact and allow the drug to permeate the coating to reach the patch.

Applicant asserts that the combination of Royds and Ishihara does not describe Applicant's invention as claimed. The combination of Royds and Ishihara does not make obvious to one of ordinary skill in the art Applicant's invention as recited in independent claims 1, 3, 52, and 57. Claims 4-13, 53, and 58-62 are also not made obvious by Royds and Ishihara because their inventive subject matter is within the scope of, and depends from, that of claims 1, 3, 52, and 57.

Applicant respectfully request the Examiner to withdraw the obviousness rejection of these claims and allow the claims

C. REJECTION OF CLAIMS 1-14, 52-54 AND 57-62 UNDER 35 U.S.C. § 103(a) AS BEING UNPAENTABLE OVER ROYDS AND ISHIHARA AND FURTHER IN VIEW OF ZEIMER.

The Examiner asserts that Applicant's invention is unpatentable over Royds and Ishihara as applied to claims 1, 3-13, 52, 53, and 57-62 and further in view of Zeimer. The Examiner asserts that Ishihara and Royds do not disclose thermal energy applied to a patch to release an encapsulated drug from a microcapsule. The Examiner asserts that Zeimer teaches that lipid vesicles irradiated by a laser beam heat the lipid vesicles causing their rupture. Therefore, the Examiner asserts that the combination of Zeimer with Royds and Ishihara make obvious Applicant's invention as recited in claims 2, 14, and 54.

Applicants respectfully disagree.

As discussed above in Section B, Royds and Ishihara do not make obvious applicants invention. The addition of Zeimer does not eliminate the defects of the other references. Therefore, the combination of Royds, Ishihara, and Zeimer does not make obvious Applicant's invention as recited in claims 2 and 14 because the subject matter depends from independent claim 1 and dependent claim 3 (which

depends from 1). Claim 54 embraces the subject matter of claim 2 and thus is not made obvious from the combination of Royds, Ishihara, and Zeimer.

Applicant respectfully request the Examiner to withdraw the obviousness rejection of claims 2, 14, and 54 as well as the remaining claims 1, 3-13, 52, 53, and 57-62 and allow all of the claims.

CONCLUSION

Applicant intends this response to be completely response to the outstanding Examiner's Action. Since Applicant has amended claims 52 and 54, and provided arguments against the obviousness rejections, prompt notice of allowance of claims 1-14, 52-54, and 57-62 is respectfully solicited. If questions remain, the Examiner is invited to telephone Applicant's undersigned attorneys.

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M.P. Moon
Reg. 53,844
Gerry J. Elman
Reg. 24,404
Customer no. 003775

Phone: 610-892-9942
efax: 925-226-4995
email: mp@elman.com
gerry@elman.com